ZADITOR - ketotifen fumarate solution
A-S Medication Solutions

DRUG FACTS

OTC - ACTIVE INGREDIENT SECTION

Ketotifen (0.025%)
(equivalent to ketotifen fumarate 0.035%)

OTC - PURPOSE SECTION

Antihistamine

INDICATIONS & USAGE SECTION

Temporarily relieves itchy eyes due to pollen, ragweed, grass, animal hair and dander.

WARNINGS SECTION

For external use only

Do Not Use

- if solution changes color or becomes cloudy
- if you are sensitive to any ingredient in this product
- to treat contact lens related irritation

WHEN USING THIS PRODUCT

- do not touch tip of container to any surface to avoid contamination
- remove contact lenses before use
- wait at least 10 minutes before reinserting contact lenses after use
- replace cap after each use

STOP USE AND ASK A DOCTOR IF YOU EXPERIENCE ANY OF THE FOLLOWING

- eye pain
- changes in vision
- redness of the eye
- itching worsens or lasts for more than 72 hours

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

If swallowed, get medical help or contact a Poison Control Center right away.

DOSAGE & ADMINISTRATION SECTION

- **Adults and children 3 years of age and older:** Put 1 drop in the affected eye(s) twice daily, every 8-12 hours, no more than twice per day.
- **Children under 3 years of age:** Consult a doctor

OTHER INFORMATION

- Only for use in the eye.
- Store between 4°-25°C (39°-77°F).

INACTIVE INGREDIENT SECTION

benzalkonium chloride 0.01%, glycerol, purified water, sodium hydroxide and/or hydrochloric acid

HOW SUPPLIED

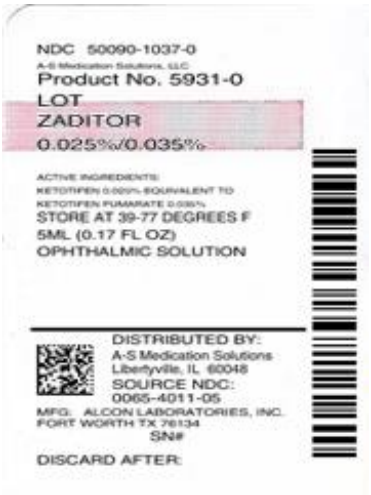
Product: 50090-1037

NDC: 50090-1037-0 5 mL in a BOTTLE, DROPPER

QUESTIONS?

call toll-free
1-800-757-9195
MedInfo@AlconLabs.com
www.zaditor.com
Serious side effects associated with use of this product may be reported to this number.

ketotifen fumarate



ZADITOR

ketotifen fumarate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-1037(NDC:0065-4011)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
KETOTIFEN FUMARATE (UNII: HBD503WORO) (KETOTIFEN - UNII:X49220T18G)	KETOTIFEN	.35 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Benzalkonium Chloride (UNII: F5UM2KM3W7)	
Glycerin (UNII: PDC6A3C0OX)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Hydrochloric Acid (UNII: QTT17582CB)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-1037-0	1 in 1 CARTON	11/28/2014	
1		5 mL in 1 BOTTLE, DROPPER ; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077200	12/21/2012	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-1037)

Revised: 11/2017 A-S Medication Solutions